

**AMINOSYN II IN DEXTROSE** - isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, proline, serine, n-acetyl-L-tyrosine, dextrose hydrous, sodium chloride, potassium chloride, magnesium chloride hexahydrate and sodium phosphate, dibasic injection, solution

**AMINOSYN II AND DEXTROSE** - isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, proline, serine, n-acetyl-L-tyrosine, dextrose hydrous, sodium chloride, potassium chloride, magnesium chloride hexahydrate and sodium phosphate, dibasic, anhydrous injection, solution

HOSPIRA, INC.

***AN AMINO ACID INJECTION WITH MAINTENANCE ELECTROLYTES IN DEXTROSE INJECTION***

**NOTE:** These solutions are hypertonic. See **WARNINGS** and **PRECAUTIONS**.

**Nutrimix® Dual-chamber Flexible Container**

**The Upper Chamber Contains 500 mL of Aminosyn II with Maintenance Electrolytes (An Amino Acid Injection with Maintenance Electrolytes)**

**The Lower Chamber Contains 500 mL of Dextrose Injection, USP**

R<sub>x</sub> only

**DESCRIPTION**

**Upper Chamber:** Contains 500 mL of Aminosyn II 3.5% M or 4.25% M (an amino acid injection with maintenance electrolytes) — a sterile, nonpyrogenic solution for intravenous infusion. Formulations are described below.

**Lower Chamber:** Contains 500 mL of Dextrose Injection, USP — a sterile, nonpyrogenic, hypertonic solution of Dextrose, USP in water for injection. The table below indicates the characteristics of this concentrated solution.

The container must be used only after removing the clamp and thoroughly mixing the contents of the two chambers. Mixing the contents of the upper and lower chambers yields a concentrated source of amino acids and carbohydrate calories for intravenous infusion. Headspace contains Nitrogen gas.

**UPPER CHAMBER COMPOSITION (500 mL)**

**Essential Amino Acids (mg/100 mL)**

<b>Aminosyn II</b>	<b>7% M*</b>	<b>8.5% M*</b>
Isoleucine	462	561
Leucine	700	850
Lysine (acetate)**	735	893
Methionine	120	146
Phenylalanine	209	253
Threonine	280	340
Tryptophan	140	170
Valine	350	425

\*Contains maintenance electrolytes.

\*\*Amount cited is for lysine alone and does not include the acetate salt.

**UPPER CHAMBER COMPOSITION (500 mL) Continued**

**Nonessential Amino Acids (mg/100 mL)**

<b>Aminosyn II</b>	<b>7% M*</b>	<b>8.5% M*</b>
Alanine	695	844
Arginine	713	865
Aspartic Acid	490	595
Glutamic Acid	517	627
Glycine	350	425
Histidine	210	255
Proline	505	614
Serine	371	450
N-Acetyl-L-Tyrosine	189	230

\*Contains maintenance electrolytes.

#### **Electrolytes (mEq/L)<sup>a</sup>**

<b>Aminosyn II</b>	<b>7% M</b>	<b>8.5% M</b>
Sodium <sup>b</sup> (Na <sup>+</sup> )	82	87.4
Potassium (K <sup>+</sup> )	26	26
Chloride (Cl#)	73	73
Magnesium (Mg <sup>++</sup> )	6	6
Phosphorus <sup>c</sup> (P)	7 (mM)	7 (mM)
Acetate <sup>d</sup> (C <sub>2</sub> H <sub>3</sub> O# <sub>2</sub> )	50.2	61
Sodium Hydrosulfite	60	60
added (mg/100 mL)		
<b>Osmolarity</b>	719	811
(actual mOsmol/L)		
pH	5.8	5.8
<b>range<sup>e</sup></b>	5.0 — 6.5	5.0 — 6.5

<sup>a</sup> Electrolyte concentrations cited in mEq/L must be divided by two in order to derive the amounts present in the 500 mL upper chamber.

<sup>b</sup> Includes sodium from the pH adjustor, sodium hydroxide, and from the antioxidant, sodium hydrosulfite.

<sup>c</sup> mM = millimoles; one mM of phosphorus = 31 mg phosphorus.

<sup>d</sup> From lysine acetate.

<sup>e</sup> Contains sodium hydroxide for pH adjustment.

#### LOWER CHAMBER COMPOSITION (500 mL)

<b>Dextrose</b>	<b>10%</b>	<b>20%</b>
<b>Injection, USP</b>	<b>Dextrose</b>	<b>Dextrose</b>
Dextrose, hydrous (g/500 mL)	50	100
Energy (kcal/500 mL)	170	340
Osmolarity (actual mOsmol/L)	546	934
pH	4.3	4.3
range	3.2 — 6.5	3.2 — 6.5

#### COMBINED ADMIXTURE COMPOSITION (1000 mL)

##### Essential Amino Acids (mg/100 mL)

<b>Aminosyn II</b>	<b>3.5% M*</b>	<b>4.25% M*</b>
Isoleucine	231	280
Leucine	350	425
Lysine (acetate)**	368	446
Methionine	60	73
Phenylalanine	104	126
Threonine	140	170
Tryptophan	70	85
Valine	175	212

\*Contains maintenance electrolytes.

\*\*Amount cited is for lysine alone and does not include the acetate salt.

**Nonessential Amino Acids (mg/100 mL)**

<b>Aminosyn II</b>	<b>3.5% M*</b>	<b>4.25% M*</b>
Alanine	348	422
Arginine	356	432
Aspartic Acid	245	298
Glutamic Acid	258	314
Glycine	175	212
Histidine	105	128
Proline	252	307
Serine	186	225
N-Acetyl-L-Tyrosine	94	115

\*Contains maintenance electrolytes.

**Electrolytes (mEq/L)**

	<b>3.5% M*</b>	<b>4.25% M*</b>
<b>Aminosyn II</b>	<b>in D5-W</b>	<b>in D10-W</b>
Sodium <sup>a</sup> (Na <sup>+</sup> )	41	43.7
Potassium (K <sup>+</sup> )	13	13
Chloride (Cl#)	36.5	36.5
Magnesium (Mg <sup>++</sup> )	3	3
Phosphorus <sup>b</sup> (P)	3.5 (mM)	3.5 (mM)
Acetate <sup>c</sup> (C <sub>2</sub> H <sub>3</sub> O# <sub>2</sub> )	25.1	30.5
Sodium Hydrosulfite	30	30
added (mg/100 mL)		
<b>Osmolarity</b> (actual mOsmol/L)	616	919
pH	5.8	5.8

<b>range<sup>d</sup></b>	5.0 — 6.5	5.0 — 6.5
Total Amino Acids (g/L)	35	42.5
Protein Equivalent (g/L)	35	42.5
Total Nitrogen (g/L)	5.35	6.5

\*Contains maintenance electrolytes.

<sup>a</sup> Includes sodium from the pH adjustor, sodium hydroxide, and from the antioxidant, sodium hydrosulfite.

<sup>b</sup> mM = millimoles; one mM of phosphorus = 31 mg phosphorus.

<sup>c</sup> From lysine acetate.

<sup>d</sup> pH adjusted with sodium hydroxide.

After admixture, the formulation contains the following added ingredients per 100 mL:

Aminosyn II 3.5% M in 5% Dextrose Injection

Aminosyn II 4.25% M in 10% Dextrose Injection

Sodium chloride, 120 mg; potassium chloride, 97 mg; magnesium chloride (hexahydrate), 30 mg; dibasic sodium phosphate (anhydrous), 49.3 mg; and sodium hydrosulfite added, 30 mg.

Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

Magnesium Chloride, USP (hexahydrate) is chemically designated MgCl<sub>2</sub>• 6H<sub>2</sub>O, deliquescent crystals very soluble in water.

Dibasic Potassium Phosphate, USP (anhydrous) is chemically designated K<sub>2</sub>HPO<sub>4</sub>, white granules very soluble in water.

Dibasic Sodium Phosphate, USP (anhydrous) is chemically designated Na<sub>2</sub>HPO<sub>4</sub>, colorless or white granular salt freely soluble in water.

Dextrose, USP is chemically designated D-glucose, monohydrate (C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>• H<sub>2</sub>O), a hexose sugar freely soluble in water.

The formulas for the individual amino acids are as follows:

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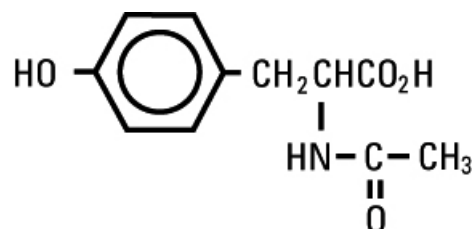
#### Essential Amino Acids

Isoleucine, USP	C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub>
Leucine, USP	C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub>
Lysine Acetate, USP	C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> • CH <sub>3</sub> COOH
Methionine, USP	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S
Phenylalanine, USP	C <sub>9</sub> H <sub>11</sub> NO <sub>2</sub>
Threonine, USP	C <sub>4</sub> H <sub>9</sub> NO <sub>3</sub>
Tryptophan, USP	C <sub>11</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub>
Valine, USP	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub>

#### Nonessential Amino Acids

Alanine, USP	C <sub>3</sub> H <sub>7</sub> NO <sub>2</sub>
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Arginine, USP	$C_6H_{14}N_4O_2$
Aspartic Acid	$C_4H_7NO_4$
	$HO_2CCH_2CH(NH_2)CO_2H$
Glutamic Acid	$C_5H_9NO_4$
	$HO_2CCH_2CH_2CH(NH_2)CO_2H$
Glycine, USP	$C_2H_5NO_2$
Histidine, USP	$C_6H_9N_3O_2$
Proline, USP	$C_5H_9NO_2$
Serine, USP	$C_3H_7NO_3$
N-Acetyl-L-Tyrosine	$C_{11}H_{13}NO_4$



The flexible plastic container is fabricated from a specially formulated nonplasticized thermoplastic co-polyester (CR3). Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions inside the plastic container also can leach out certain of its chemical components in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.

### CLINICAL PHARMACOLOGY

Aminosyn II 3.5% M or 4.25% M in Dextrose Injection obtained upon mixing thoroughly the contents of the two chambers, provides carbohydrate calories and crystalline amino acids to stimulate protein synthesis, to limit protein catabolism, to minimize liver glycogen depletion and to promote wound healing. The infusion of this mixture through a central or peripheral venous line should be considered to approximate the protein and calorie requirements for patients receiving total parenteral nutrition. I.V. lipids may be infused simultaneously to provide adequate calories, if desired.

### INDICATIONS AND USAGE

Aminosyn II 3.5% M or 4.25% M in Dextrose Injection is indicated for intravenous infusion in the prevention of nitrogen loss and negative nitrogen balance in cases where (a) the gastrointestinal tract by the oral, gastrostomy or jejunostomy route cannot or should not be used, (b) gastrointestinal absorption of nutrients is impaired or (c) metabolic requirements for protein and calories are substantially increased as with extensive burns and (d) morbidity and mortality may be reduced by replacing amino acids lost from tissue breakdown, thereby preserving tissue reserves, as in acute renal failure. In such patients intravenous feeding for more than a few days would be expected.

The addition of supplemental electrolytes such as trace metal additives, or multivitamin additives will be in accordance with the prescription of the attending physician.

### CONTRAINDICATIONS

This preparation should not be used in patients with hepatic coma or metabolic disorders involving impaired nitrogen utilization.

## **WARNINGS**

Aminosyn II 4.25% M in 10% Dextrose Injection is hypertonic, but it may be delivered by peripheral vein only if lipid emulsion is administered simultaneously.

Intravenous infusion of amino acids may induce a rise in blood urea nitrogen (BUN), especially in patients with impaired hepatic or renal function. Appropriate laboratory tests should be performed periodically and infusion discontinued if BUN levels exceed normal postprandial limits and continue to rise. It should be noted that a modest rise in BUN normally occurs as a result of increased protein intake.

Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, metabolic alkalosis, prerenal azotemia, hyperammonemia, stupor and coma.

Administration of amino acid solutions in the presence of impaired renal function may augment an increasing BUN, as does any protein dietary component.

Solutions containing sodium ion should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Solutions containing potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

Solutions containing acetate ion should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

Solutions of Aminosyn II 3.5% M or 4.25% M in Dextrose Injection contain sodium hydrosulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

(Admixtures of Aminosyn II 3.5% M or 4.25% M in Dextrose Injection with an amino acid concentration greater than 2.5% are too concentrated for administration to infants.)

Instances of asymptomatic hyperammonemia have been reported in patients without overt liver dysfunction. The mechanisms of this reaction are not clearly defined, but may involve genetic defects and immature or subclinically impaired liver function.

**WARNING:** This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

## **PRECAUTIONS**

Special care must be taken when administering glucose to diabetic or prediabetic patients. To control and minimize hyperglycemia and consequent glycosuria, it is desirable to monitor blood and urine glucose and, if necessary, add insulin.

Because of its antianabolic activity, concurrent administration of tetracycline may reduce the nitrogen sparing effects of infused amino acids.

Intravenously administered amino acids should be used with caution in patients with history of renal disease, pulmonary disease, or with cardiac insufficiency so as to avoid excessive fluid accumulation.

Nitrogen intake should be carefully monitored in patients with impaired renal function.

## **SPECIAL PRECAUTIONS FOR CENTRAL INFUSIONS**

**ADMINISTRATION BY CENTRAL VENOUS CATHETER SHOULD BE USED ONLY BY THOSE FAMILIAR WITH THIS TECHNIQUE AND ITS COMPLICATIONS**

Central vein infusion of nutrient solutions requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of complications. Attention must be given to solution preparation, administration and patient monitoring. **IT IS ESSENTIAL THAT A CAREFULLY PREPARED PROTOCOL BASED ON CURRENT MEDICAL PRACTICES BE FOLLOWED, PREFERABLY BY AN EXPERIENCED TEAM.**

### **SUMMARY HIGHLIGHTS OF COMPLICATIONS**

(See also Current Medical Literature).

#### **1. Technical:**

The placement of a central venous catheter should be regarded as a surgical procedure. One should be fully acquainted with various techniques of catheter insertion. For details of technique and placement sites, consult the medical literature. X-ray is the best means of verifying catheter placement. Complications known to occur from the placement of central venous catheters are pneumothorax, hemothorax, hydrothorax, artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arteriovenous fistula, phlebitis, thrombosis and air and catheter emboli.

#### **2. Septic:**

The constant risk of sepsis is present during administration of total parenteral nutrition. It is imperative that the preparation of the solution and the placement and care of catheters be accomplished under strict aseptic conditions. Solutions should be used promptly after mixing. Storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.

Administration time for a single container and set should never exceed 24 hours.

#### **3. Metabolic:**

The following metabolic complications have been reported: metabolic acidosis and alkalosis, hypophosphatemia, hypocalcemia, osteoporosis, hyperglycemia, hyperosmolar nonketotic states and dehydration, glycosuria, rebound hypoglycemia, osmotic diuresis and dehydration, elevated liver enzymes, hypo- and hypervitaminosis, electrolyte imbalances and hyperammonemia in children. Frequent evaluations are necessary especially during the first few days of therapy to prevent or minimize these complications.

Administration of glucose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma and death.

### **Pregnancy Category C.**

Animal reproduction studies have not been conducted with Aminosyn II with maintenance electrolytes in dextrose injection. It is not known whether this admixture can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Aminosyn II 3.5% M or 4.25% M in Dextrose Injection should be given to pregnant women only if clearly needed.

### **Pediatric Usage**

Due to their concentration, these solutions are not recommended for use in pediatric patients less than 1 year old. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

### **Geriatric Use**

Clinical Studies of Aminosyn II 3.5% M or 4.25% M in Dextrose Injection have not been performed to determine whether patients over 65 years of age respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by kidney, and the risk for adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

**CLINICAL EVALUATION AND LABORATORY DETERMINATIONS, AT THE DISCRETION OF THE ATTENDING PHYSICIAN, ARE NECESSARY FOR PROPER MONITORING DURING ADMINISTRATION.** Do not withdraw venous blood for blood chemistries through the infusion site, as interference with estimations of nitrogen-containing substances may occur. Blood studies should include glucose, urea nitrogen, serum electrolytes, ammonia, cholesterol, acid-base balance, serum proteins, kidney and liver function tests, osmolality and hemogram. White blood count and blood cultures are to be determined if indicated. Urinary osmolality and glucose should be determined as necessary.

Do not use unless the solutions are clear and container is undamaged. Discard unused portion.

Do not use if solution in either chamber is discolored or if clamp is open or missing.

This product contains no more than 25 mcg/L of aluminum.

## **ADVERSE REACTIONS**

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause mental confusion and/or loss of consciousness.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Generalized flushing, fever and nausea also have been reported during peripheral infusions of amino acid solutions.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

## **OVERDOSAGE**

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS and PRECAUTIONS.

## **DOSAGE AND ADMINISTRATION**

The total daily dose of Aminosyn II 3.5% M or 4.25% M in Dextrose Injection to be infused depends on daily protein and caloric requirements and on the patient's metabolic and clinical response. In many patients, provision of adequate calories in the form of dextrose may require the administration of exogenous insulin to prevent hyperglycemia and glycosuria. To prevent rebound hypoglycemia, a solution containing 5% dextrose should be administered when hypertonic dextrose infusions are abruptly discontinued.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

As with all intravenous fluid therapy, the parenteral administration of a solution of amino acids and dextrose requires an accurate estimate of the total fluid and electrolytes needed to compensate for the patient's measurable urinary and other (i.e., nasogastric suction, fistula drainage, diarrhea) daily losses. After estimating the total daily fluid (water) requirements, the appropriate volume to be infused to meet the daily protein requirement of the patient can be determined. The balance of fluid needed beyond the volume of the amino acid/dextrose solution can be provided by other solutions suitable for intravenous infusion. I.V. lipid emulsions may also be infused to deliver additional calories if required. Lipid emulsion can be administered to provide up to 3 g fat/kg/day, infused simultaneously with Aminosyn II 3.5% M or 4.25% M in Dextrose Injection by means of a Y-connector located near the infusion site, using separate flow controls for each solution. Aminosyn II 3.5% M or 4.25% M in Dextrose Injection may be premixed with fat emulsion, but only in the 2000 mL Nutrimix II container. Vitamins and trace minerals may be added to the amino acid/dextrose solution as needed.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

The total daily dose of the amino acid/dextrose solution to be infused depends on daily protein requirements and on the patient's metabolic and clinical response. The daily determination of nitrogen balance and accurate body weights, corrected for fluid balance, are probably the best means of assessing individual protein requirements.

### **Adult Patients**

The daily nutrient requirements of an average adult patient, not hypermetabolic, in an acceptable weight range and with restricted physical activity, are about 30 kcal/kg of body weight, 12 to 18 grams of nitrogen (or 1.0 to 1.5 g amino acids/kg/day) and between 2500 and 3000 mL of fluids. In depleted and severely traumatized patients such as burned patients or patients who have received major surgery with complications, the requirements for nutrients and fluids may be significantly higher. In such cases, 4000 calories and 25 grams of nitrogen or more may be required daily to achieve nitrogen balance. The fluid losses through drainages and wound surface must be taken into account in calculating the fluid requirements of these patients.

Fat emulsion administration should be considered when prolonged parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD). Serum lipids should be monitored for evidence of EFAD in patients maintained on fat-free TPN.

The infusion rate for central vein admixtures of Aminosyn II 4.25% M in Dextrose Injection should be 2 mL/min initially and may be gradually increased to deliver the required amounts of amino acids and calories. If nutrient administration falls behind schedule, under no circumstances should an attempt to "catch up" to planned intake be made. The rate of nutrient infusion is governed by the protein requirements and by the patient's glucose tolerance estimated by glucose levels in plasma and urine. The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg/hour; at a rate of 0.8 g/kg/hour, about 95% of the infused dextrose is retained. Administration of exogenous insulin may be required in order to control hyperglycemia and glycosuria which may occur upon infusion of concentrated glucose solutions. When concentrated dextrose infusion is abruptly interrupted rebound hypoglycemia may occur, which can be prevented by the administration of 5% or 10% dextrose solutions. Part of the caloric requirements may be met by the infusion of I.V. fat emulsions.

SERUM ELECTROLYTES SHOULD BE MONITORED AS INDICATED. Electrolytes may be added to the nutrient solution as indicated by the patient's clinical condition and laboratory determinations of plasma values. Major electrolytes are sodium, chloride, potassium, phosphorus, magnesium and calcium. With the exception of calcium, all of the aforementioned electrolytes are contained in the Aminosyn II 3.5% M or 4.25% M. A calcium supplement is recommended for central vein nutritional admixtures. Alternate electrolyte additives may be used at the clinician's discretion.

Vitamins, including folic acid and vitamin K are required additives. The trace element supplements should be given when long-term parenteral nutrition is undertaken.

Iron is added to the solution or given intramuscularly in depot form as indicated. Vitamin B<sub>12</sub>, vitamin K and folic acid are given intramuscularly or added to the solution as desired.

In patients with hyperchloremic or other metabolic acidosis, sodium and potassium may be added as the acetate or lactate salts to provide bicarbonate alternates.

In adults, hypertonic mixtures of amino acids and dextrose may be safely administered by continuous infusion through a central venous catheter with the tip located in the vena cava.

### **Pediatric**

Due to their concentration, these solutions are not recommended for use in pediatric patients less than 1 year old. Pediatric requirements for parenteral nutrition are constrained by the greater relative fluid requirements of the infant and greater caloric requirements per kilogram. Pediatric patients greater than 1 year old generally receive a 2 to 2.5% amino acid solution, but older pediatric patients can tolerate amino acids in concentrations of up to 5%. Dosage is usually prescribed on a g/kg body weight/day basis and patient age as follows: ages 1 to 3 years, 2 to 2.5 g/kg/day; ages 4 to 12 years, 2 g/kg/day; ages 13 to 15 years, 1.7 g/kg/day; ages 16 and above 1.5 g/kg/day. Energy requirements for children between 1 and 7 years of age are approximately 75 to 90 kcal/kg/day; for children 7 to 12 years of age, 60 to 75 kcal/kg/day; and for ages 12 to 18 years, 30 to 60 kcal/kg/day. Energy intake may be supplemented with intravenous fat emulsion. In cases of malnutrition or stress, these requirements may be increased.

Supplemental electrolytes and vitamin additives should be administered as deemed necessary by careful monitoring of blood chemistries and nutritional status. Iron supplementation is more critical in the child than the adult because of the increasing red cell mass required by the growing child. Serum lipids should be monitored for evidence of essential fatty acid deficiency in patients maintained on fat-free TPN. Bicarbonate should not be administered during infusion of the nutritional solution unless deemed absolutely necessary.

To ensure the precise delivery of the small volumes of fluid necessary for total parenteral nutrition in children, accurately calibrated and reliable infusion systems should be used.

### **Drug Interactions**

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

### **INSTRUCTIONS FOR USE**

**DO NOT USE IF AMINOSYN II IS DISCOLORED OR IF CLAMP IS OPEN OR MISSING. COLOR VARIATION IN THE DEXTROSE INJECTION FROM PALE YELLOW TO YELLOW IS NORMAL AND DOES NOT ALTER EFFICACY.**

#### **To Open:**

Tear outer wrap at notch. After removing the overwrap, check for minute leaks by squeezing the container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

#### **To Add Medication:**

Additives may be incompatible. See DOSAGE AND ADMINISTRATION.

1. Prepare the appropriate additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area through inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive ports should be protected by covering with additive caps.
4. Mix container contents thoroughly.

### **Preparation for Administration**

#### **(Use aseptic technique)**

1. Open clamp between the two chambers. Completely drain all the solution and air into the lower chamber. To achieve this, stretch the side wall of the emptied top chamber. Close clamp after draining.
2. Close flow control clamp of administration set.
3. Remove cover from outlet port at bottom of container.
4. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE:** See full directions on administration set carton.
5. Suspend from hanger at top of container.

6. Squeeze and release drip chamber to establish proper fluid level in chamber.
7. Open flow control clamp to expel air from set. Close flow control clamp.
8. Connect to central infusion catheter.
9. Regulate rate of administration with flow control clamp. Ensure that all solution and air are in the lower chamber when reading fluid levels.

**WARNING: Do not use flexible container in series connections.**

#### HOW SUPPLIED

The Nutrimix<sup>®</sup> dual-chamber flexible container provides 500 mL of Aminosyn II 3.5% M or 4.25% M in the upper chamber and 500 mL of Dextrose Injection, USP in the lower chamber. Concentrations provided in the separate chambers and in the combined 1000 mL volume after release of the clamp and mixing are shown below.

List No.	Concentrations		Concentrations		Total Admixture Volume
	Prior to Admixture		Following Admixture		
	Aminosyn II	Dextrose	Aminosyn II	Dextrose	
7740	7% M*	10%	3.5% M*	5%	1000 mL
7742	8.5% M*	20%	4.25% M*	10%	1000 mL

\*Contains maintenance electrolytes.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40° C does not adversely affect the product.

**Avoid exposure to light.**

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